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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,588	01/16/2001	Melton B. Affrime	AL01132K	4299

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/25/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,588	AFFRIME ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-20,22-25,27-39,41-46,48,49 and 51-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *31-39,41-44,56 and 57* is/are allowed.

6)☒ Claim(s) *1-9,11-20,22-25,27-30,45,46,48,49,51-55 and 58-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

The following is responsive to the request for continued examination under 37 CFR 1.114, the request for reconsideration and declaration received May 14, 2003.

No claims are cancelled. No new claims are added. Claims 1-9, 11-20, 22-25, 27-39, 41-46, 48, 49 and 51-64 are pending.

Information Disclosure Statement

Applicant's Information Disclosure Statement received May 14, 2003 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Correction of Inventorship

Applicant's Request to correct Inventorship submitted under 37 CFR 1.48(a)(2) has been considered and entered.

Response to Request for Consideration and the Declaration

The previous claim rejection under 35 USC 103(a) set forth in paragraphs 1-3 of The office action mailed Nov. 20, 2002 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The declaration of Dr. Gupta filed May 14, 2003 is effective to remove the abstracts to Herron et al. and Padhi et al. In view of the declaration, these abstracts are no longer available as prior art under 102(a) as these abstracts are no longer publications by "another."

However, upon further consideration of the claims, the following new ground(s) of rejection is submitted.

The indicated allowability of claims 19-20, 22-23, 29, 30, 61-64 is withdrawn in view of the following new ground(s) of rejection.

New Ground(s) of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-9, 11-14, 61-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to method of treating and/or preventing allergic and inflammatory conditions of the skin or airway passages in a human of 12 years or older by administering an effective amount of desloratadine. The claimed methods of treatment and/or prevention fail to meet the requirement for an adequate written description of the claimed invention as required by 35 USC, 112, paragraph 1.There is insufficient descriptive support for the generic limitation “allergic and inflammatory conditions of the skin or airway passages” Furthermore, the claimed methods require treatment of unspecified diseases and no evidence indicates that a treatable disease,

other than urticaria, atopic dermatitis, allergic rhinitis, sinusitis, asthma, etc. (please see page 8, lines 12-18 of the specification) was known to Applicant. In the absence of some understanding of other inflammatory conditions to be treated one of ordinary skill in the art would not have concluded that Applicant was in possession of the claimed methods.

2. Claims 1-9, 11-14, 15-20, 22-25, 29, 30 61-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The claims are drawn to methods of preventing allergic and inflammatory conditions of the skin or airway passages, such as a cold, non-allergic rhinitis, allergic rhinitis or seasonal or perennial allergic rhinitis, in a human of 12 years or older

comprising administering effective amounts of desloratadine. Please see the specification, page 8, line 9-18.

(2) **The state of the prior art**

Concerning the prevention of colds (which falls within the limitation of "allergic and inflammatory conditions of the skin or airway passages), it is known that a cold involves a viral infection of the upper respiratory tract. There are several types of viruses, i.e. DNA viruses and RNA viruses, each of which function differently. According to Goodman & Gilman's, effective agents for treating viral infections have a limited spectrum of activity and target a specific viral protein (please see page 1192; lines 13-16 of the left column). Therefore, for example, an "antiviral" agent effective against herpes would not necessarily treat an HIV infection. Since, the art recognizes the difficulty/unpredictability in "treating" viral infections, "prevention" would be no less difficult or unpredictable. Furthermore, the prevention of colds has not been recognized and thus accepted in the art.

Moreover, according to Pharmacotherapy, A Pathophysiologic Approach, avoidance of offending allergens is the best method of preventing allergic rhinitis. However, this is too difficult or impractical. Therefore, common therapeutic approaches for treating allergic rhinitis are directed at relief of symptoms. Please see page 947, **Treatment; Avoidance and Treatment/Prevention of Symptoms**.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical and chemical art is high.

(5) The breadth of the claims

The claims are broad and encompass treatment and prevention of allergic and inflammatory conditions of the skin or airway passages, such as colds (viral infection).

(6) The amount of direction or guidance presented

Applicant's specification does not provide guidance for the prevention of conditions such as colds, which involve viral infections as well as allergic and non-allergic rhinitis. The specification provides no guidance to enable one of ordinary skill in the art to use the invention commensurate in scope with the claims, which, as stated above, are broad and encompass numerous conditions. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." Applicant's specification does not set forth a representative number of examples of conditions, which can be prevented or treated by the claimed compound desloratadine.

(7) The presence or absence of working examples

There are no working examples, in vivo or in vitro, in the specification relating to the prevention of the claimed disorders. Nor are there a representative number of

working examples drawn to the treatment of the numerous disorders encompassed by some of the claims.

(8) The quantity of experimentation necessary

Since (1) the prevention of colds has not been recognized in the art, and the prevention of conditions such as allergic and non-allergic rhinitis is often difficult and impractical, with the therapeutic approach limited to the treatment and prevention of symptoms; and (2) since compound structure and activity for pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine which disorders are prevented or treated by desloratadine as well as which of the many conditions of the skin or passageway encompassed by claims 1 and 61 are treated or prevented by desloratadine.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-9, 11-18, 24-25, 27-28, 45-46, 48-49, 51-55 and 58-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,432,972 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and USPN '972 claims methods for treating allergic and inflammatory conditions of the airway passages such as seasonal allergic rhinitis, perennial allergic rhinitis, sinusitis and allergic asthma by administering effective amounts of desloratadine.

The difference between the instant application and USPN '972 is that USPN '972 specifically claims a method of treating congestion associated with allergic and inflammatory conditions of the airway passages such as perennial or seasonal allergic rhinitis and allergic asthma.

However, the scope of the claims instant application and the claims of USPN '972 overlap because the claims of the instant application are broader and encompass the more specific claims of USPN '972. Furthermore, at least 4 of the conditions treated in the instant application are identical to those claimed in USPN '972. Also, the claimed treatment of "congestion" in USPN '972 falls within the treatment of "nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis" claimed in the instant application. Finally, the specific plasma concentration limitations in the claims of the instant application are encompassed by the generically claimed desloratadine administration step of USPN '972.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 703-306-3227. The examiner can normally be reached on Tue-Thur. from 8:30 to 6:00. The examiner can also be reached on alternate Mondays .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725 The fax phone number for the organization where this application or proceeding is assigned is 703-308-7924.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

CDM

Sept. 19, 2003

JAMES
PRIMARY EXAMINER